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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,938	07/25/2006	Sven Klussmann	021315-08630401	2223

78018 7590 08/24/2009

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POST OFFICE BOX 2630
MONTGOMERY VILLAGE, MD 20886-2630

EXAMINER	
PANDE, SUCHIRA	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
08/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,938	KLUSSMANN ET AL.	
	Examiner	Art Unit	
	SUCHIRA PANDE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-12 and 31-72, 75-90* is/are pending in the application.

4a) Of the above claim(s) *8,10-12,31-72,75-78 and 82-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,7,9 and 79-81* is/are rejected.

7)☒ Claim(s) *81* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Applicant has amended claims 1, 4, 6, 7, 8, 9, 10, 11 and 12 have been amended. Claims 2-3, 5, 13-30 have been cancelled. Applicant has added new claims 79-90; claims 31-78 and 82-90 are withdrawn. Out of remaining claims 1, 4, 6-12 and 79-81 only claims 1, 4, 6, 7, 9 and 79-81 are commensurate with elections made on September 23, 2008. Hence claims 1, 4, 6, 7, 9 and 79-81 will be examined in this action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 1/30/2009 was filed after the mailing date of the non final action on December 2, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

Sequence Rules Compliance

3. The amendment to specification, CRF along with CRF statement filed on June 2, 2009 are acceptable. This amendment puts the specification in compliance with the sequence rules.

Response to arguments

Re election of Species

Election/Restrictions

4. In the response filed on September 23, 2008 for the restriction requirement mailed by Examiner on June 24, 2008 Applicant elected

a. Species of the type of nucleic acid (claim 1 is generic)

option i. wherein the nucleic acid is a L-nucleic acid (claim 7).

Applicant had made the election without traverse. At the time of restriction Examiner had clearly separated elements of claim 8 which read upon the normal chirality i.e. D-nucleic acids from the L-nucleic acid. Hence Applicants arguments are not persuasive and Examiner will restrict to search to only L-nucleic acid and not extend it to elements recited in claim 8. Hence claim 8 properly remains withdrawn.

Regarding second election Applicant elected

b. Species of nucleic acid based on structure (claim 1 is generic)

option v. wherein the nucleic acid has a secondary structure shown in Fig. 1B (claim 9).

Applicant had made the election without traverse. At the time of restriction Examiner had clearly separated elements of claims 10-12 from element claimed in claim 9. Hence Applicants arguments are not persuasive and Examiner will restrict the search to the secondary structure shown in Fig. 1B as claimed in claim 9 and not extend it to elements recited in claims 10-12. Hence claims 10-12 properly remains withdrawn.

Consequently only claims 1, 4, 6, 7, 9 and 79-81 commensurate with above elections will be examined in this action.

Re Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Instant Application is national stage entry of PCT Ser. No EP04/12739 filed 10 November 2004. Applicant also claims priority to EP Ser. No 03025743.0 filed November 10, 2003, certified English translation of which has been received. Hence for prior art purposes instant application has a priority date of November 10, 2003.

Re 112 1st written description rejection of claims 1-2, 4-7 and 9

Re 102 (e) rejection of claims 1-2, 4-7 and 9 over Helmling et al. (WO 2004/013274 A2 as evidenced by Bednarek et al.

6. Applicant has amended claim 1 to add elements that were not examined before. Amended claim 1 currently recites:

A nucleic acid which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin, wherein said nucleic acid comprises SEQ ID NO:I.

Since previously cited rejections do not address these limitations, accordingly they are not valid any more and hence are being withdrawn.

Re provisional double patenting rejection of claim 1 over claim 1 of copending application 10/522, 582

7. Applicant has amended claim 1 to include sequence of SEQ ID No 1. This aspect was not analyzed before hence a priori it seems that double patenting rejection of claim 1 over claim 1 of copending application 10/522,582 is obviated by this amendment. Hence the double patenting rejection cited before is being withdrawn.

Claim Interpretation

8. Product claims are being prosecuted in the instant application. Applicant has not defined or described what structural feature of nucleic acid comprising SEQ ID NO 1 is required to discriminate a bioactive n-octanoyl ghrelin from a non-bioactive des-ocatonoyl ghrelin. Hence for application of prior art purposes Examiner is interpreting that any art that teaches a nucleic acid that specifically binds to n-octanoyl ghrelin and comprises SEQ ID NO 1 inherently teaches a nucleic acid which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-ocatonoyl ghrelin.

Claim Objections

9. Claim 81 is objected to because of the following informalities: The newly added claim appears to depend from only one claim recited namely claim 7. If this is the intent, then the claim should read

----according to claim 7------.

The words "any of" should be deleted to make the claim language unambiguous. However if the intent is to make the claim dependent from multiple claims, then appropriate claim numbers should be added to instant claim 81. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 4, 6, 7, 9 and 79-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite a nucleic acid which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin, wherein said nucleic acid comprises SEQ ID NO: I . By specifying the SEQ ID NO 1, a priori it would appear as if Applicant was in possession of the claimed invention. The SEQ ID NO 1 is 48 mer with following recited sequence

```
cgugygnagg yanaaaacnu aarwccgaag guaaccawuc cuacnacg SEQ ID NO 1
```

Only 5 positions are represented by either y, r, or w. So at these positions either of the two appropriate nt can be substituted. So the number of sequence becomes 5^2 = 25.

At 4 positions that are represented by n any of the 4 nucleotides can be substituted. So that means a 4^4 = 16 possible variants are possible of the SEQ ID NO 1.

Hence total no permutations of variants of SEQ ID NO 1 based on above representation is 25 x 16 = 400. Further on last paragraph of page 4 of the specification Applicant teaches 4 insertion loci Ins1 to 4 are permitted in the derived SEQ ID NO 1 sequence. The maximum number of nucleotides associated with above loci are:

Ins1 = 0-30

Ins2 = 0-14

Ins3 = 1-3

Ins4 = 0-2

Since each of these can be any nucleotide. Therefor each Ins is represented by a maximum of

30^4 =810000 variants of Ins1,

14^4 = 38416 variants of Ins2,

3^4 = 81 variants of Ins3 and

2^4 = 16 variants of Ins4.

So it is clear from the above calculations that the total number of sequences represented by the claimed SEQ ID NO 1 are over a million.

Data is provided for 1 nucleic acid sequence used in Example 4 that shows this sequence discriminates between bioactive ghrelin and non bioactive ghrelin. But specification as filed does not provide any guidance to one of ordinary skill in the art as to which of these above over million possible variants claimed by SEQ ID NO 1 contains

the requisite features that will allow the nucleic acid made by them to discriminate between bioactive and non bioactive ghrelin. It would clearly require undue experimentation if one of ordinary skill in the art has to make all the above (over a million) nucleic acids and then test each of them in the assay taught in Example 4 to determine whether the nucleic acid can discriminate between bioactive ghrelin and non bioactive ghrelin.

Further claim 1 has been amended to include limitation -----wherein said nucleic acid sequence comprises SEQ ID NO: 1." One of ordinary skill in the art is provided the sequence of SEQ ID NO 1. The instant claim is written using open language "comprising". Which means other sequences can be present in addition to the claimed SEQ ID NO1. The specification as filed does not provide any written description for the length of the sequence. If the sequence comprising the SEQ ID NO: 1 is 100-1000 or if it is 1000-10,000 bases long or longer will this sequence be still able to discriminate between a bioactive and non bioactive ghrelin? In other words no written description is provided about final length constraints of the claimed nucleic acid sequence. Since claims 4, 6, 7, 9 and 79-81 depend from claim 1, hence they share the same problem.

Thus Examiner concludes that at the time of filing Applicant was not in possession of all the numerous variants claimed currently in claim 1. This is a written description rejection.

12. Claims 1, 4, 6, 7, 9 and 79-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims: Claim 1 is very broad and recites a nucleic acid which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin, wherein said nucleic acid comprises SEQ ID NO:I.

Data is provided for 1 nucleic acid sequence used in Example 4 that shows this sequence discriminates between bioactive ghrelin and non bioactive ghrelin. Thus specification as filed teaches only 1 example of nucleic acid as described in Example 4 which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin. The sequence of the nucleic acid described in example 4 is a species of the genus of nucleic acids claimed be SEQ ID NO 1. See written description rejection above where Examiner is enumerated in detail the total no of sequences encompassed by instant SEQ ID NO: 1.

So 1 sequence out of more than a million claimed discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin. But specification as filed does not provide any guidance to one of ordinary skill in the art as to which of these above over million possible variants claimed by SEQ ID NO 1 contains the requisite features that will allow the nucleic acid made by them to discriminate between bioactive

and non bioactive ghrelin. It would clearly require undue experimentation if one of ordinary skill in the art has to make all the above (over a million) nucleic acids and then test each of them in the assay taught in Example 4 to determine whether the nucleic acid can discriminate between bioactive ghrelin and non bioactive ghrelin;

(B) The nature of the invention: The invention pertains to nucleic acids that bind to bioactive ghrelin. Normally ghrelin is a peptide that binds to its receptor growth hormone secretagogue (GHS) receptor, it is not a DNA binding peptide or aptamer. Since the nucleic acid claimed discriminates between the octanoylated ghrelin and des octanoylated ghrelin, presumably the nucleic acid can somehow distinguish the presence of octanoyl group from the absence of octanoyl group. Only claim 6 limits the location of octanoylation on ghrelin molecule to serine at position 3 via ester bond. The rest of the claims 1, 4, 7 and 9 are directed to nucleic acids that may bind to octanoyl group which may be present anywhere on the ghrelin molecule. Specification as filed provides example of nucleic acid that discriminates the presence of octanoyl group on location 3 of serine in ghrelin from a ghrelin that does not contain octanoyl group at this location. No information is provided to one of ordinary skill in the art about the remaining 27 amino acids of the 28 amino acid ghrelin peptide. A nucleic acid that will bind to Octanoyl group on any of the other 27 amino acids is also encompassed by the current recitation of claims. Specification as filed teaches one of ordinary skill in the art that one nucleic acid taught in Example 4 can discriminate the bioactive n-octanoyl ghrelin containing octanoyl group at location 3 serine from a non-bioactive des-octanovl ghrelin lacking the octanoyl group at location 3 serine of ghrelin peptide. No information is

provided to one of ordinary skill by the specification as filed about the bioactivity of the of ghrelin molecules that may contain octonylation at any of the other 27 locations? Are these molecules bioactive? What happens if the octonylation is at multiple sites on ghrelin molecule are these molecules still bioactive? Hence one of ordinary skill in the art has multiple substrates (ghrelin molecules with above types of octonylation pattern) whose bioactivity status is not known. To that add the ambiguity described above about SEQ ID NO 1 sequence that discriminates the bioactive ghrelin from non bioactive ghrelin and one of ordinary skill in the art does not know which kind of sequences to make so that it will function as described in claim 1.;

(C) The state of the prior art; Prior art only teaches when octonyl group is present at serine 3 via an ester bond in ghrelin molecule then it serves as a ligand for its growth-hormone secretagogue receptor. While des –n-octanoyl ghrelin lacking this octonylation at serine 3 does not serve as a ligand for its growth-hormone secretagogue receptor. (see Hosoda et al. 2000 Biochemical and Biophysical Research communications 279: 909-913). Prior art does not teach about activity of ghrelin that may have octanoylation in other locations of ghrelin;

(D) The level of one of ordinary skill in the art is high;

(E) The level of predictability in the art: Since ghrelin is not a DNA binding peptide, hence prior art does not provide any guidance about the features required in the nucleic acid that will allow it to bind and discriminate the bioactive ghrelin from non bioactive ghrelin. Specification only teaches one example of nucleic acid out of over a million possible nucleic acid sequences claimed that can do this discrimination. Hence

one of ordinary skill has no binding motifs or criteria to use as a guideline to predict which of the possible nucleic acids claimed will meet the criteria. Thus level of unpredictability in the art is very high.;

(F) The amount of direction provided by the inventor: as enumerated above inventor has provided very limited guidance by only disclosing one nucleic acid sequence that meets the criteria;

(G) The existence of working examples: Only one working example namely example 4 is provided where discrimination between bioactive and non bioactive ghrelin by nucleic acid is taught; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: As enumerated above the number of possible nucleic acid binding sequences claimed by recitation of SEQ ID NO 1 is more than a million. One of ordinary skill in the art would have to test each of those sequences in the assay taught in Example 4 by Applicant to determine whether the nucleic acid meets the discrimination criteria claimed or not. This in view of Examiner amounts to undue experimentation.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Hence Examiner concludes the specification as filed does not enable one reasonably skilled in the art to make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Since claims 4, 6, 7, 9 and 79-81 depend from claim 1, hence they share the same enablement problems enumerated above.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1, 4, 6-7, 9 and 79-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Helmling et al. (WO 2004/013274 A2 filed as application PCT/EP2003/008542 with international filing date August 1, 2003 and priority back to August 1, 2002 cited by Applicant in IDS) as evidenced by Bednarek et al. (2000) J. Med. Chem 43: 4370-4376 provided to applicant previously).

Regarding claim 1, Helmling et al. teach a nucleic acid which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin, wherein said nucleic acid comprises SEQ ID NO:I. (see title. See page 1 par. 2 where it is taught that Octonylation of N terminus serine 3 is required for interaction of ghrelin with its receptor. Thus Helmling et al. teach octonylated ghrelin as the bioactive ghrelin. See page 8 par.

2 where nucleic acids binding specifically and with high affinity to ghrelin are taught. By this teaching of nucleic acids binding specifically and with high affinity to ghrelin Helmling et al. teach a nucleic acid which discriminates a bioactive n-octanoyl ghrelin from a non-bioactive des-octanovl ghrelin.

Helmling et al. teach a ghrelin-binding sequence SEQ ID NO: 14 which is 47 mer long whose alignment with SEQ ID NO: 1 of instant invention (48 mer) is shown below:

```
ADJ92918
ID   ADJ92918 standard; RNA; 47 BP.
AC   ADJ92918;
PN   WO2004013274-A2.

SQ   Sequence 47 BP; 18 A; 11 C; 10 G; 0 T; 8 U; 0 Other;


Qy    1 CGUGYGN AGGYAN  AAAACN UAARWCCGAAGGUAACCAWUCCUACN ACG 48mer SEQ ID 1

Db    1 CGUGUG  AGGCAAU AAAACA UAAGUCCGAAGGUAACCAAUCCUAC  ACG 47mer SEQ ID 14
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Since Applicant teaches in page 4 of the specification that insertions are possible in 4 places in the sequence of SEQ ID NO 1.

The first insertion region being the location marked by N at position 7 of SEQ ID NO 1. Where N can be 0-30. So sequence taught by Helmling et al. SEQ ID NO 14 has 0 nt at this location, indicated by a gap in Seq ID no 14.

The second region of insertion is again indicated by N at position 13 of SEQ ID NO 1. Where N can be 0-14. Thus SEQ ID 14 taught by Helmling et al. has 2 nucleotides at this location so here N=2 (AU) shown in the sequence.

The third region of insertion is again indicated by N at position 19 of SEQ ID NO 1. Where N can be 1-3. In case of SEQ ID 14 taught by Helmling et al. the sequence has one nt indicated by (A) at this position.

The fourth region of insertion is again indicated by N at nt 45 of SEQ ID NO 1. Where N can be 0-4. So in case of the SEQ ID NO 14 taught by Helmling et al. the N=0.

Thus SEQ ID NO 14 taught by Helmling et al. shows a 100% match to the claimed Sequence of SEQ ID NO 1.

Hence all the elements of claim 1 as currently presented are taught by Helmling et al.

Regarding claim 4, Helmling et al. teach the nucleic acid according to claim 1 ,wherein the binding is expressed as a Kd value, wherein the Kd of the nucleic acid is from 10 pM to 1 μM (see page 11 par. 2 where Kd of the nucleic acid is from 10 pM to 1 μM is taught).

Regarding claim 6, Helmling et al. teach wherein the n-octanoyl moiety of the n-octanoyl ghreiin is attached through an ester bond to Ser at position 3 of ghrelin. (see page 24 target molecule where Octanoyl residude is shown linked to Ser3 of ghrelin. Thus teaching n-octanoyl moiety of the n-octanoyl ghrelin is attached through an ester bond to Ser at position 3 of ghrelin). Helmling et al. do not explicitly describe wherein the n-octanoyl moiety of the n-octanoyl ghrelin is attached through an ester bond to Ser at position 3 of ghrelin.

Regarding claim 6, Bednarek et al. evidence the fact that the n-octanoyl ghrelin is attached through an ester bond to Ser at position 3 of ghrelin (see page 4371 where sequence of human ghrelin is depicted with octanoyl ghrelin shown attached to Ser at position 3 of ghrelin. Further see page 4372 last par. where Bednarek et al. teach that ghrelin is posttranslationally modified, through acylation of the hydroxyl group of Ser 3

by n-octanoic acid. In this situation, the bond formed between the OH group of serine and N-octanoic acid (whose sequence is shown in page 4371) through acylation can only result in an ester bond. The conclusion reached by Examiner that n-octanoic acid is connected to Ser3 via an ester bond in the ghrelin is further corroborated by statement on page 4374, where Bednarek et al. state "to evaluate a role of the ester bond in the side chain of residue 3----". Thus Bednarek et al. teach wherein the n-octanoyl moiety of the n-octanoyl ghrelin is attached through an ester bond to Ser at position 3 of ghrelin).

Regarding claim 7, Helmling et al. teach wherein the nucleic acid is an L-nucleic acid. (See page 12 last section on the page where generation of L-nucleic acid that binds to ghrelin is taught).

Regarding claim 9, Helmling et al. teach wherein the nucleic acid has a secondary structure shown in Fig. 1B. (See page 29/61 of the Figures where Fig. 19 of Helmling et al. is depicted. The secondary structure labeled as clone B11trc is shown on right. This clone B11trc has a secondary structure that is 100% identical to the secondary structure shown in Fig. 1B of instant application).

Regarding claim 79, Helmling et al. teach wherein the Kd of the nucleic acid is from 100 pM to 500 nM. (see page 11 par. 2 where Kd of 10 pM or higher are taught. Thus teaching a lower limit of 10 pM and they teach the Kd of nucleic acid of the invention is below 1 μM = 1000 nM. Thus teaching an upper limit of the Kd to be 1 μM. By teaching Kd below 1000 nM Helmling et al. teach the upper limit which is below 1000nM. Thus teaching the claimed range of 100 pM to 500 nM)

Regarding claim 80, Helmling et al. teach wherein the Kd of the nucleic acid is from 1 nM to 100 nM (see page 11 par. 2 last line where Kd of 1 nM to 100 nM is taught).

Regarding claim 81, Helmling et al. teach wherein the L-nucleic acid is a spiegelmer (see page 19 legend of Fig.28 where spiegelmer is taught).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of the copending Application No. 10/522,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the applications contain claims directed to a nucleic acid which binds ghrelin. At the outset Examiner would like to point out that in

instant application Applicant is using the term "bioactive ghrelin" while in Application 10/522, 582 the Applicant is using the term "ghrelin" both these terms are referring to same molecule.

This is evidenced by the fact that in Application 10/522, 582 par. 0002 it is stated "Ghrelin is a highly basic 28 amino acid peptide hormone with an octanoyl acid side chain at the third amino acid of its N-terminus (serine 3). This unusual modification is required for the interaction at the GHS-receptor and its activity." The same molecule with an octanoyl acid side chain at the third amino acid of its N-terminus (serine 3). is being referred to as bioactive ghrelin in the instant application.

With this in mind, it is clear that claim 1 of instant application is broader as it is directed to a nucleic acid which binds to a bioactive ghrelin. This claim 1 in instant application is limited to a specific SEQ ID NO 1. As shown above by Examiner this SEQ ID NO 1 encompasses more than a million sequences.

The claim 1 of the copending application 10/522,582 is narrower in scope as it limits the sequence of nucleic acid to SEQ ID NO 8 that binds to ghrelin.

Thus claim 1 of instant application is genus claim while the claim 1 of the copending application 10/522,582, is claiming one specific SEQ ID that binds ghrelin. Since species anticipates the genus hence claim 1 of instant application drawn to a nucleic acid which binds bioactive ghrelin is obvious over the claim 1 of the copending application 10/522,582.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. All claims under consideration 1, 4, 6, 7, 9, and 79-81 are rejected over prior art.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

/Teresa E Strzelecka/

Primary Examiner, Art Unit 1637

August 17, 2009